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Chronic venous leg ulcer care. Putting the patient at the heart of leg ulcer care. Part 2: Development and evaluation of the consultation template.

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Abstract:	This article, Part 2, summarises the final two phases of a study that explored the lived experiences of patients with leg ulcers and the impact of the condition on their quality of life. Early phases revealed a mismatch between issues that impacted on quality of life for a patient with chronic venous leg ulceration and their disclosure during subsequent consultations. In response to findings, a nominal group technique was employed to facilitate the development of a new leg ulcer consultation template with patient partners, to include many of the issues raised in phases 1. The new template was subsequently evaluated in terms of its utility, significance and clinical potential. Application of the new template during routine consultations, appears to encourage patient disclosure of issues that are of important to them and may otherwise have been overlooked.
Suggested Reviewers:	
Response to Reviewers:	Responses to reviewer comments: Sticky note suggestions from both reviewers actioned. Reviewer #1: I also have concerns about the second part of the study that has not been addressed in the article's text. These are as follows: 2 DNs, 2 TVNs and a nurse academic experienced in consultations were involved in the nominal group. This has been made clearer. The weakness of patient participants being involved but outside of the nominal group has been rewritten to state that they were patient partners. Any reference to being

	<p>developed by patients has been removed. The impact of this has been mentioned.</p> <p>The researcher undertook all outcome measures during phase 4 - this has been made clearer.</p> <p>Attempts have been made to reduce research jargon to a minimum - this has taken into account the background of readers, but some is essential.</p> <p>Table 5 has been retained but some sections have been reduced and arrows added to indicate the direction of scores. The explanation has been simplified. Hopefully this is clear now.</p> <p>The LUCT is a simple tool to focus the consultation. A study phase evidenced some improvement but the clinical opportunity to evaluate the LUCT demonstrated real changes to treatment based on the prompting the LUCT provided. Feedback here was anecdotal from staff, but I feel that this still has value. I have reworded to indicate that this was no more than an evaluation in real time.</p> <p>I have reworded the discussion to reflect the study outcomes.</p> <p>Recommendation for further study of patient benefit of LUCT is now included.</p> <p>Reviewer #2: Reference to part 1 reduced although, ideally, these should be read consecutively.</p> <p>Review of literature relating to PCC and tools to involve patients more readily has been included. This supports the rationale to develop the template.</p> <p>Sections reorganised to ensure a logical flow.</p> <p>Statistical sections rewritten to ensure ease of understanding for all readers.</p> <p>Discussion section rewritten. Limitations of the study made explicit. Reference made to other published studies where appropriate.</p>
Additional Information:	
Question	Response
Please enter the word count of your manuscript	4724

QUALITY OF LIFE & LEG ULCERATION TEMPLATE.**Patient Name:****Date:**

Please complete this template every four weeks, unless your patient's condition changes.
Assess the themes below with your patient. Record any interventions you make, advice that you give or problems that you solve in the comments boxes. Guidance regarding completion is provided overleaf.

Assessment of mobility & ability to get out & about:

Are you able to mobilise as you did prior to having an ulcer?

Yes: ☐ No: ☐ If not, what stops you?

Are you able to get out and about and socialise as you did?

Yes: ☐ No: ☐ Comments:**Assessment of sleep, nutrition and pain:**

Where are you sleeping?

Bed: ☐ Chair: ☐ Comments:

Do you sleep well? If not, what stops you from sleeping?

Yes: ☐ No: ☐ Comments:

Are you eating a normal diet? If not, why?

Yes: ☐ No: ☐ Comments:

Is your pain better or worse since your last visit?

Better: ☐ Worse: ☐ Comments:

What pain killers are you taking? Do you take these regularly?

Medication dose & frequency taken:

Are they effective?

Yes: ☐ No: ☐ Comments:**Assessment of personal hygiene, clothes & shoes:**

Are you managing to shower or bathe?

Yes: ☐ No: ☐ Comments:

Are you able to wear the clothes and shoes that you did prior to having an ulcer?

Yes: ☐ No: ☐ Comments:

If not, what are you wearing? Is this suitable?

Comments:

Assessment of emotional effects, relationships & fears:

Do your ulcers get you down? How are you feeling today?

Yes: ☐ No: ☐ Comments:

Do you have friends or family members who support you?

Comments:

Do you have any concerns about your ulcer?

Comments:

Assessment of wound management:

Have you documented your patient's treatment and the advice you have given to them in their notes?

Yes: ☐ No: ☐ Comments:

Are your patient's legs wet? Is there any odour?

Yes: ☐ No: ☐ Comments:

Are the dressing type and frequency of dressings appropriate?

Comments:

Have you made your patient aware of their wound assessment and their management plan?

Yes: ☐ No: ☐ Comments:

Template assessment guidance.**Assessment of mobility & ability to get out & about:**

- Are leg ulcers restricting mobility? Are you able to recommend anything to assist with mobility?
- Is your patient able to enjoy the activities that they did prior to having an ulcer? Is there anything you can recommend to improve this?

Assessment of sleep, nutrition and pain:

- Does the ulcer interfere with sleep? What advice have you given? eg. the timing of analgesia, positioning, etc. Where are they sleeping? Is this suitable?
- Is dietary intake sufficient? Is a full nutritional assessment necessary? Have suitable supplements been prescribed?
- Assess your patient's pain and ascertain whether this is improving or deteriorating? Is it intermittent or continuous? What makes the pain better or worse?
- What analgesia is currently being taken and is this effective? Does the medication need reviewing? What advice have you given in relation to non-pharmacological methods of pain relief such as positioning of the limb, timing of the visit, etc.?

Assessment of personal hygiene, clothes & shoes:

- Is your patient able to maintain their personal hygiene? Can you make any recommendations to improve this? Is it possible for legs to be washed or for any aids and appliances to be recommended?
- Is your patient struggling to wear clothes and shoes that they would like to? Is their footwear safe? Review any advice given.

Assessment of emotional effects, relationships & fears:

- How is your patient feeling today and how is their ulceration impacting on their daily life? Is there anything you can offer to support your patient?
- Does your patient confide in friends and family about their ulcers and do they feel well supported?

Assessment of wound management:

- Complete a full assessment of the wound and document the details in the patients' notes.
- Assess exudate and odour – are the dressing product suitable and the frequency of visits appropriate? How are these symptoms impacting on your patient?
- Does your patient understand their management plan and do they agree with this? Are they able to follow the advice given?

Problem solving / comments:

- This box is provided to record any problems that you have solved during your visit today. This may have been by making a referral to another service, undertaking a reassessment, giving advice or making a recommendation or by making a change to treatment in response to a problem that you have assessed. Discuss and agree your actions and the plan of care with your patient and document here.

Review the assessments you make, the advice you give and the interventions you recommend at each visit.**Comments and problem solving:**

Completed by.....Signed(nurse).....Signed(patient).....

**Chronic venous leg ulcer care.
Putting the patient at the heart of leg ulcer care.
Part 2: Development and evaluation of the consultation template.**

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Key words:

Consultation, leg ulcers, person-centered, quality of life.

Abstract.

Abstract revised to the format required for Part 1 (for Community Wound Care).

This article, Part 2, summarises the final two phases of a study that explored the lived experiences of patients with leg ulcers and the impact of the condition on their quality of life. Early phases revealed a mismatch between issues that impacted on quality of life for a patient with chronic venous leg ulceration and their disclosure during subsequent consultations. In response to findings, a nominal group technique was employed to facilitate the development of a new leg ulcer consultation template with patient partners, to include many of the issues raised in phases 1. The new template was subsequently evaluated in terms of its utility, significance and clinical potential. Application of the new template during routine consultations, appears to encourage patient disclosure of issues that are of important to them and may otherwise have been overlooked.

This study is reported in two articles:

Chronic venous leg ulcer care. Putting the patient at the heart of leg ulcer care.

Part 1. Exploring the consultation.

and

Chronic venous leg ulcer care. Putting the patient at the heart of leg ulcer care.

Part 2: Development and evaluation of the consultation template.

A copy of the template can be accessed at: www.keele.ac.uk/luct

Chronic venous leg ulcer care.
Putting the patient at the heart of leg ulcer care.
Part 2: Development and evaluation of the consultation template.

Introduction

As evidenced in Part 1, chronic venous leg ulcers (CVLU) pose a significant challenge to the patient, the clinical team and to healthcare budgets (Posnett & Franks, 2007; Guest et al, 2015; Franks et al, 2016). Specifically, for the patient, their quality of life (QoL) is diminished, due to the range of symptoms and recurrent nature of CVLUs (Rich & McLachlan, 2003; Persoon et al, 2004; Guest et al, 2015; Green et al, 2018). Care is predominantly focused on the wound rather than the many 'other' consequences of having a CVLU (Rich & McLachlan, 2003; Briggs & Fleming, 2007; Ashby et al, 2014).

This series of two articles (Part 1 and 2) summarise a four-phase study which received ethical approval from Mid Staffordshire Local Research Ethics Committee, with data collected between 2010 and 2013. Here, in Part 2, phases 3 and 4 are presented and, ideally, should be read in conjunction with part 1. Phase 3 employed a nominal group meeting, with patient partners, to develop a Leg Ulcer Consultation Template (LUCT), with consensus from participants. The final phase of the study, adopted a within-subjects design to explore the feasibility and utility of the LUCT, across a small group of patients. In addition, a small scale clinical application of the template is also presented which demonstrates some potential for implementation of the LUCT into clinical practice.

Background.

Patient- or person-centred care (PCC) is recognised as a high priority for the provision of health care; essential to the delivery of a quality service and key to ensuring patient safety (Pelzang, 2010; World Health Organisation (WHO), 2015). In 2015, the WHO called for a paradigm shift in the delivery of health care to a system that is based on patient preference and coordinated around their needs. WHO (2015, p.7) described the required approach as 'people-centred health services', an approach where 'people have the education and support they need to make decisions and participate in their own care. It is organized around the health needs and expectations of people rather than diseases.'

For the most part, in the United Kingdom (UK), we describe this approach, often interchangeably, as either patient- or person-centred care (PCC). Indeed, PCC describes a relationship between the health care professional (HCP) and the patient and their family or carers, where the focus is on the patient's wellbeing, their psychological and social situation, and their experience of their illness (Stewart et al, 2000). Although a dated definition, this remains at the crux of PCC. The relationship Stewart et al (2000) describes is only achieved when decision-making is shared, and care focuses on the patient as a person, not just their disease (Stewart et al, 2000; Lewin et al, 2009).

Research evidences that patients value a person-centred approach to their care; both patients and carers are able to demonstrate a better understanding of their condition, they are more likely to be involved in decision-making and more concordant with mutually agreed treatment plans (Stewart et al, 2000; Dieppe et al, 2002; Irwin & Richards, 2006; Lewin et al, 2009; WHO, 2015). Despite such evidence, further exploration suggests HCPs continue to fail to consistently elicit patients' concerns or to negotiate their treatment options (Ley et al, 1976; Mead & Bower, 2000; Stewart et al,

2000; Entwistle & Watt, 2006; Lewin et al, 2009; Green et al, 2013b; Santana et al, 2017) and, importantly, patients are often reluctant to disclose their concerns during clinical consultations (Bugge et al, 2006; Green et al, 2013b; Wolf et al, 2017).

It appears that this situation is intensified when a patient suffers from multiple conditions, with patients and carers reporting fragmented care, where HCPs focus on treating one disease or condition in isolation (McCabe, 2004; de Haes, 2006; Santana et al, 2017; WHO, 2017). McCormack and McCance (2006) provide a conceptual framework to support the principles of PCC, which they describe as being characterised by the principle of “being in relation”, with an optimal patient-centred relationship based on flexibility, mutuality, transparency and negotiation. Santana et al (2017) and WHO (2017) have similarly published conceptual frameworks and advocate that their application provides a ‘road map’ to guide the provision of PCC.

Recommendations to enhance PCC have tended to focus on interventions that aim to change HCP behaviour, such as enhancing their consultation style (EPOC, 2008) or on patient-mediated interventions, that, when applied, might motivate the patient (McAllister et al, 2004; Kinnersley et al, 2007; McCaffery et al, 2007; DeWalt et al, 2009; O’Connor, 2009). The latter approach, to motivate the patient to share decision making, include approaches such as checklists, educational materials, self-management tools, training and decision aids: all of which are viewed as being superior to normal care (Irwin & Richards, 2006). Checklists are reported to be well evaluated across complex conditions, particularly at the end of life, and are known to have a positive impact on patient satisfaction and quality of life (QoL) (Hegel et al, 2008; Dilworth et al, 2011; WHO 2017).

The benefits of the use of a checklist, for both the patient and their carer, are their potential to move any consultation with a HCP from being symptom-focused and HCP-led, to a consultation that is both experience-focused and patient-centred (Irwin & Richards, 2006; Wolf et al, 2017). Use of patient-mediated interventions, such as a checklist, can ensure that patient-focused issues are addressed, health issues are tackled in a timely manner, seamless care and concordance are enhanced (WHO, 2017). Indeed, Wolf et al (2017, p.1) concludes that ‘patients appear to value a process of human connectedness above and beyond formalised aspects of documenting agreed goals and care planning. PCC increases patients’ confidence in professionals who are competent and able to make them feel safe and secure.’

Phase 3

The aim of phase 3 was to develop a consultation template, with consensus, in response to earlier study findings. Phases 1 and 2 had established that patients failed, on many occasions, to disclose issues that were of concern to them during their routine wound consultations; this was despite these issues being freely revealed, unprompted, during the phase 1 unstructured interviews (Green et al, 2013 a & b; Green et al, 2018). On occasions, it was evidenced, issues were raised by the patient but were inadvertently overlooked or inadequately addressed by the nurse; in these situations, issues raised were then ‘lost’, they went unnoticed and solutions were not fully offered.

Phase 3 was designed to involve clinical colleagues and patients in the development of a new, patient-focused template, to be known as the Leg Ulcer Consultation template

(LUCT), to encourage the consulting nurse to raise and explore appropriate issues with the patient during their routine wound care consultations. The intention was that the template would prompt patient disclosure, activate patients to engage with their care and promote a concordant relationship between the patient and their health care professional (Stewart et al, 2000; Morden et al, 2012; Green et al, 2013 a & b; Wolf et al, 2017).

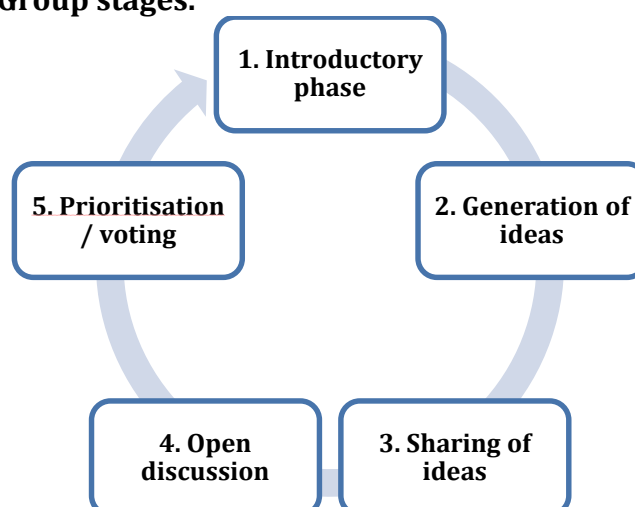
To ensure the template's utility, a nominal group (NG) approach was employed (Carney et al, 1996). This technique was selected as it is known to be efficient, requires minimal preparation, is cost effective and is undertaken in a face-to-face meeting (Vella et al, 2000; Potter et al, 2004). Although NG meetings are most often small-scale, with between 5 and 9 members, they are known to have the potential to reveal views that may representative of the wider community (Lancaster et al, 2002; Carey & Asbury, 2012).

The initial intention of the nominal group was to involve both expert HCP and patient members in a single meeting. Expert members of the NG included two DNs who were experienced in the care of patients with CVLU, a nurse academic experienced in the development of consultation tools and two Tissue Viability Nurse (TVN) Specialists. All members were sampled purposively to ensure they held the requisite skills and knowledge required in the development of the resource. Each was provided with verbal and written study information and an opportunity to consent.

Three patient participants also agreed to take part in this phase, having already been involved in phases 1 and 2. They were approached by their District Nurse (DN) and provided with the study information. Once consented, however, they all requested to be seen individually, outside of the face-to-face group meeting as they felt that they would be reluctant to contribute freely alongside experts. It is acknowledged that this was contrary to the model of a NG and is a weakness to this phase, however, this decision is potentially not surprising when the literature related to power relationships between patients and HCPs is explored (Henderson, 2003).

The NG approach has five clear stages (Carney et al, 1996) (Figure 1).

Figure 1: Nominal Group stages.



Prior to the NG meeting, a small amount of pre-reading was circulated to all members, both expert and patient; this ensured that all were prepared to engage from an informed

viewpoint. The expert meeting commenced with a summary of background information, with regular opportunities provided for participants to share their ideas. This was a fast-paced process that ensured that all members had the opportunity to contribute, with ideas explored by group members and, finally, items prioritised for inclusion in the template (Carney et al, 1996).

In response to the patient request and following the expert meeting, the researcher undertook individual meetings with each of the patient partners where each undertook a 'read through' of the template, in real time as it would be applied during a consultation situation. This is known as 'Thinking Aloud' methodology (Lundgren-Laine & Salantera, 2010) and is based on the model developed by Newell and Simon (1972). It is a recognised research method that encourages participants to verbalise their thoughts whilst exploring a new checklist and provides an insight into thoughts, knowledge and understanding of the participant on the utility of a new checklist. The patient participants were very engaged with the process and provided constructive comments; one participant, suggested minor amendments to wording and more space in the comments/problem solving section; the other two patient participants agreed these alterations and confirmed that the template was useful, easy to understand and reflected the issues that impacted on their lives each day. The researcher relayed patient partner suggestions to the 'expert' group members via email, as an iterative process, and the template was amended accordingly, with consensus, until a final version was agreed by all.

The iterative process of template development included decisions on the wording of questions, to ensure that effective cues were provided for the consulting nurse. The format and layout of the template was considered, in detail, including ease of completion with the aim to avoid unnecessarily extending consultations. All NG members agreed to the inclusion of additional guidance for question completion and the grouping of similar questions to facilitate exploration of related themes simultaneously. The question groupings were agreed and, to an extent, reflect the activities of daily living; a familiar structure for DNs which may encourage completion (Roper et al, 2000).

- (i) mobility, ability to get out and to socialise;
- (ii) sleep, diet and pain;
- (iii) personal hygiene and issues with clothes and shoes;
- (iv) emotional effects of ulceration, relationships and fears;
- (v) documentation of care provided, exudate and odour, type of dressings and information given to the patient.

Consensus was reached, a factor that underpins the NG technique, and the new template was agreed (Figure 2). The format included a range of response options from tick boxes to additional comments (Carney et al, 1996). The final section for completion was entitled 'comments and problem solving'; this section aimed to encourage the nurse to record any goals that had been jointly agreed with their patient and would require review during subsequent consultations. The final template was two sides of A4 paper and encompassed all of the features identified by the NG.

Figure 2: Consultation Template (Green et al, 2015).

QUALITY OF LIFE & LEG ULCERATION TEMPLATE. Patient Name: _____ Date: _____	
<p>Please complete this template every four weeks, unless your patient's condition changes. Assess the themes below with your patient. Record any interventions you make, advice that you give or problems that you solve in the comments boxes. Guidance regarding completion is provided overleaf.</p>	
<u>Assessment of mobility & ability to get out & about:</u>	
Are you able to mobilise as you did prior to having an ulcer?	
Yes: <input type="checkbox"/>	No: <input type="checkbox"/> If not, what stops you? <input style="width: 150px;" type="text"/>
Are you able to get out and about and socialise as you did?	
Yes: <input type="checkbox"/>	No: <input type="checkbox"/> Comments: <input style="width: 150px;" type="text"/>
<u>Assessment of sleep, nutrition and pain:</u>	
Where are you sleeping?	
Bed: <input type="checkbox"/>	Chair: <input type="checkbox"/> Comments: <input style="width: 150px;" type="text"/>
Do you sleep well? If not, what stops you from sleeping?	
Yes: <input type="checkbox"/>	No: <input type="checkbox"/> Comments: <input style="width: 150px;" type="text"/>
Are you eating a normal diet? If not, why?	
Yes: <input type="checkbox"/>	No: <input type="checkbox"/> Comments: <input style="width: 150px;" type="text"/>
Is your pain better or worse since your last visit?	
Better: <input type="checkbox"/>	Worse: <input type="checkbox"/> Comments: <input style="width: 150px;" type="text"/>
What pain killers are you taking? Do you take these regularly?	
Medication dose & frequency taken: <input style="width: 150px;" type="text"/>	
Are they effective?	
Yes: <input type="checkbox"/>	No: <input type="checkbox"/> Comments: <input style="width: 150px;" type="text"/>
<u>Assessment of personal hygiene, clothes & shoes:</u>	
Are you managing to shower or bathe?	
Yes: <input type="checkbox"/>	No: <input type="checkbox"/> Comments: <input style="width: 150px;" type="text"/>
Are you able to wear the clothes and shoes that you did prior to having an ulcer?	
Yes: <input type="checkbox"/>	No: <input type="checkbox"/> Comments: <input style="width: 150px;" type="text"/>
If not, what are you wearing? Is this suitable?	
Comments: <input style="width: 150px;" type="text"/>	
<u>Assessment of emotional effects, relationships & fears:</u>	
Do your ulcers get you down? How are you feeling today?	
Yes: <input type="checkbox"/>	No: <input type="checkbox"/> Comments: <input style="width: 150px;" type="text"/>
Do you have friends or family members who support you?	
Comments: <input style="width: 150px;" type="text"/>	
Do you have any concerns about your ulcer?	
Comments: <input style="width: 150px;" type="text"/>	

Have you documented your patient's treatment and the advice you have given to them in their notes?

Yes: ☐ No: ☐ Comments:

Are your patient's legs wet? Is there any odour?

Yes: ☐ No: ☐ Comments:

Are the dressing type and frequency of dressings appropriate?

Comments:

Have you made your patient aware of their wound assessment and their management plan?

Yes: ☐ No: ☐ Comments:

Assessment of mobility & ability to get out & about:

- Are leg ulcers restricting mobility? Are you able to recommend anything to assist with mobility?
- Is your patient able to enjoy the activities that they did prior to having an ulcer? Is there anything you can recommend to improve this?

- Does the ulcer interfere with sleep? What advice have you given? eg, the timing of analgesia, positioning, etc. Where are they sleeping? Is this suitable?
- Is dietary intake sufficient? Is a full nutritional assessment necessary? Have suitable supplements been prescribed?
- Assess your patient's pain and ascertain whether this is improving or deteriorating? Is it intermittent or continuous? What makes the pain better or worse?
- What analgesia is currently being taken and is this effective? Does the medication need reviewing? What advice have you given in relation to non-pharmacological methods of pain relief such as positioning of the limb, timing of the visit, etc.?

- Is your patient able to maintain their personal hygiene? Can you make any recommendations to improve this? Is it possible for legs to be washed or for any aids and appliances to be recommended?
- Is your patient struggling to wear clothes and shoes that they would like to? Is their footwear safe? Review any advice given.

- How is your patient feeling today and how is their ulceration impacting on their daily life? Is there anything you can offer to support your patient?
- Does your patient confide in friends and family about their ulcers and do they feel well supported?

- Complete a full assessment of the wound and document the details in the patients' notes.
- Assess exudate and odour – are the dressing product suitable and the frequency of visits appropriate? How are these symptoms impacting on your patient?
- Does your patient understand their management plan and do they agree with this? Are they able to follow the advice given?

- This box is provided to record any problems that you have solved during your visit today. This may have been by making a referral to another service, undertaking a reassessment, giving advice or making a recommendation or by making a change to treatment in response to a problem that you have assessed. Discuss and agree your actions and the plan of care with your patient and document here.

Comments and problem solving:

Completed by.....Signed(nurse).....Signed(patient).....

Phase 4:

The aim of this final phase of the study was to explore the best method of evidencing the utility of the template in the future. This feasibility phase was undertaken across the same two geographic areas as earlier phases, however, as so often happens within the National Health Service (NHS), these areas had now merged to form one large Primary Care Trust (PCT). As it was envisaged that recruiting a sample may be a challenge in such a period of change, a 'within-subjects' design was applied (Hicks, 2009) which, since the sample acts as its' own control, allows for a reduced number of participants.

New DN participants were required for this phase, who were experienced, willing to be involved, to have a caseload including suitable CVLU patients and, importantly, to not have been involved in earlier phases. Suitable participants were identified by their Nurse Managers, with study information and consent forms supplied. Teams undergoing major reorganisation were excluded, where possible, but this introduced many challenges in gaining a sample. Once the DNs had consented to take part, they selected patients on their caseload who met the inclusion criteria: having a CVLU for more than 6 weeks (Vowden & Vowden, 2001) and not having been involved in earlier phases.

Eventually, despite many challenges, two study teams were recruited:

1. Location 4 (L4): a busy, inner city clinic that served several GP practices with a single nurse who was trained in wound care and provided care at a daily wound care clinic.
2. Location 5 (L5): a busy DN team of four registered nurses providing domiciliary visits and also providing a daily clinic.

Across these two teams, despite frequent prompting, only nine patient participants were recruited:

1. L4 recruited five patients. All patients were all seen in a wound care clinic.
2. L5 recruited four patients. Three were seen at home and one attended a wound care clinic.

Seven participants were male, two female and they had a median age of 68 years (range 34 - 87 years). It is acknowledged that the pilot sample was small and constituted a major limitation to the study, however, difficulties in recruitment, at the time, were as a result of a period of major regional reorganisation, with a number of teams merging and staff being relocated.

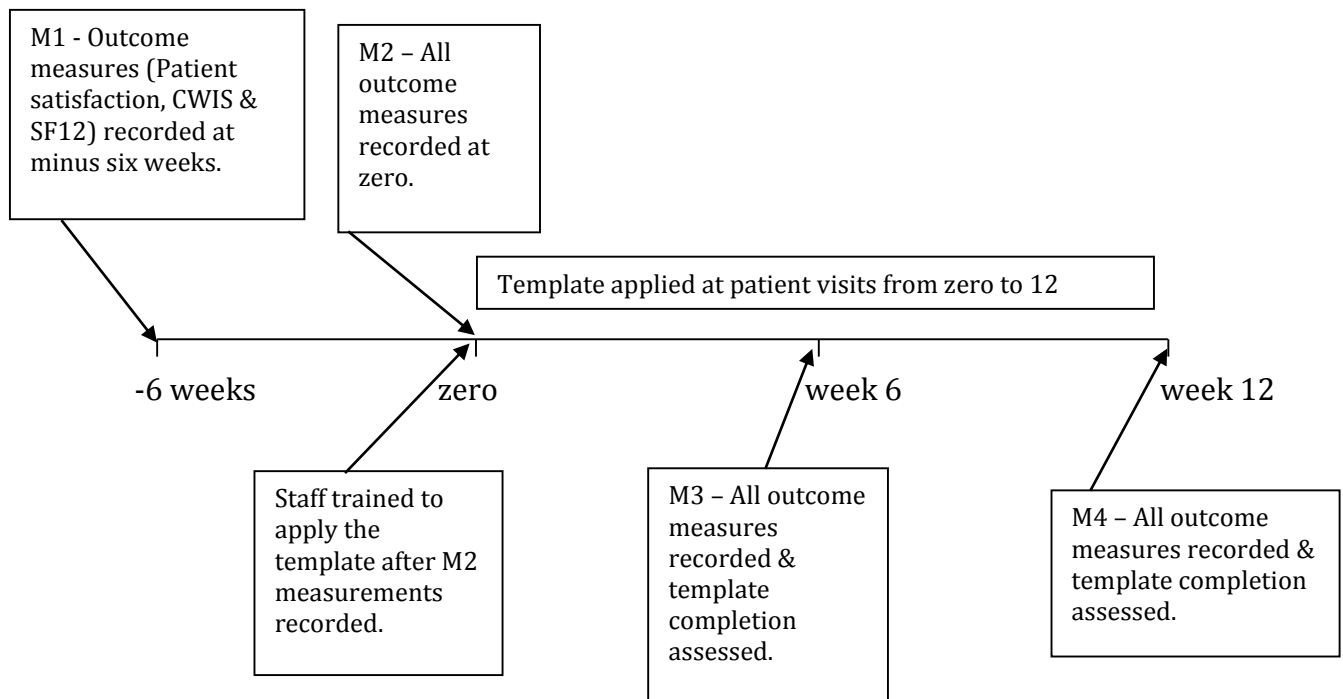
As said, in view of these limitations, the pilot study applied a 'within-subjects design' (Hicks, 2009) which accommodates a smaller sample size. The exploration of LUCT utility aimed to ascertain its impact, and since it was felt that this would be evidenced in both patient satisfaction and QoL, over time, these were selected as outcome measures for this feasibility phase. Patient satisfaction was selected as the primary outcome measure, with QoL the secondary (Mead & Bower, 2000; Bowling, 2005).

The study was undertaken over an 18-week period (Figure 3). Outcomes were assessed at four distinct time intervals, each six weeks apart, allowing for a six week 'control' period at the start of the study. At each interval, the following four validated instruments were completed:

- (i) Poulton's (1996) adapted Consultation Satisfaction Questionnaire (CSQ)
- (ii) Medical Short Form 12 (SF-12) (Ware et al, 1996)
- (iii) EuroQol 5D (EQ 5D) (EuroQol, 1990)
- (iv) Cardiff Wound Impact Scale (CWIS) (Price & Harding, 2004)

All tools were reliable, valid and sensitive to changes in care delivery (Bowling, 2005). It is acknowledged that utilising four instruments was potentially burdensome for patient participants, however, it was envisaged that the study findings would serve to indicate the most appropriate tool to be used, if a full study were to take place in the future. The researcher distributed the instruments (i-iv) at each time interval, either during a clinic visit or at the patients' home and assisted with completion if the participant required.

Figure 3: Pilot timeline.



During the first six weeks of the study, the participant's wound care consultations were unchanged, with nurse participants unaware of the template. The four outcome tools (i-iv) were completed at the start (M1) and after six weeks (M2). This period provided two sets of scores and constituted the control period, as care remained unchanged (Figure 3). A mean of these scores (M1/M2) was calculated to provide a single control score for each participant; this single score was deemed acceptable since it was assumed that scores would remain relatively stable during this control period as care was unchanged.

At week 6, the intervention, application of the LUCT, commenced following short training session for nurse participants to familiarise themselves with the principles of LUCT application. Following the training, each of the nurse participants used the LUCT during consecutive consultations with each the consenting patient participants for the next 12 weeks. Outcome measures were recorded at the 12th week (M3) and 18th week (M4),

providing a total of three outcome scores overall (a mean of M1/M2, M3 & M4). For the purpose of this paper, only M1/M2 and M4 are reported.

The 'within-subject design' provides data which, when analysed, indicates the change of outcome measures over time. Preliminary analysis indicated scores were not normally distributed, so the non-parametric Wilcoxon Signed Rank Test was applied, a test specifically designed for paired data (Hicks, 2009; Pallant, 2007). Application of the Wilcoxon Signed Rank Test converts scores at each time interval to ranks (Z) and compares them, allowing for the calculation of an effect size (Lancaster et al, 2002; Thabane, 2010; Leon et al, 2011). The effect size is represented by r on a scale of 0 to 1 (Pallant, 2007): $r=0.1$, represents a small effect; $r=0.3$, represents a medium effect and $r=0.5$, represents a large effect.

A single control score (mean of M1/M2) was calculated, and, the difference between this and the final score (M4) was calculated. A range of statistical information is provided but, for the purpose of the significance of any change, the p value and r value (effect size) are reported here (Pallant, 2007) (Table 5).

Table 5: Wilcoxon Signed Rank Test between M1/M2 and M4.

		M1/M2 (mean score)	M4 (Wk18 score)	p value	r: effect size s=small (0.1) m=medium (0.3)
Consultation Satisfaction Questionnaire (CSQ)	CSQ General Satisfaction	95.83	100 ↑	0.34	0.19 (s-m)
	CSQ Professional care	97.5	100 ↑	0.89	0.03 (s)
	CSQ Depth of relationship	97.5	100 ↑	0.83	0.04 (s)
	CSQ Length of consultation	95.83	100 ↑	0.74	0.0 (s)
SF-12	Physical Health score	34.65	34.85 ↑	0.77	0.06 (s)
	Mental Health score	48.53	45.07 ↓	0.17	0.27 (s-m)
EuroQoL 5D	EQ5D score	0.57	0.57 -	0.17	0.27 (s-m)
	EQ Visual Analogue score	57.5	60 ↑	0.78	0.06 (s)
Cardiff Wound Impact Schedule (CWIS)	CWIS QoL score	6.5	7.0 ↑	0.35	0.18 (s-m)
	CWIS Satisfaction scale	5.0	7.0 ↑	0.4	0.16 (s-m)
	CWIS Well being	41.07	50 ↑	0.31	0.2 (m)
	CWIS Physical symptoms	58.33	71.88 ↑	0.52	0.13 (s)
	CWIS Social life	83.92	96.42 ↑	0.67	0.08 (s)

Promisingly, over this feasibility study, data revealed that all but two of the outcome scores (SF-12 Mental Health score and EQ-5D score) demonstrated an increase over the intervention period (week 6 to week 18), when compared to the control 'mean' score (M1/M2) (indicated by the arrows in the M4 column). It should be noted that the intervention period was relatively short, 12 weeks, so it was unsurprising that scores over this time period, although demonstrating a positive, improving trend, failed to achieve statistical significance (indicated by the p value).

Overall, over this short feasibility study, the effect sizes (or r value) for both outcome measures were small (0.1) to medium (0.3) ($r=0.03-0.27$), which indicates that there was some clinical impact on the patient outcomes, both satisfaction and QoL, as a result of the

application of the LUCT. In addition to the quantitative data from the pilot, both patient and nurse participants provided positive anecdotal feedback as to the utility of the template and its potential clinical significance.

The strengths of phase 4 were the adoption of an appropriate design and that outcome measures were recorded by the researcher during face to face meetings, enhancing response rates and completion. However, challenges with recruitment, during a period that coincided with extensive NHS reorganisation, limited sample size recruitment which, in turn, limited the generalisability of the findings.

Clinical application of the LUCT.

Evidence suggests that the efficacy of PCC interventions can be assessed either by their impact on patient experience, as demonstrated above, but also in terms of the satisfaction of the HCP with their consultation experience and subsequent outcomes. Phase 4 findings demonstrated a small to medium effect on consultation satisfaction and QoL, as a result of the application of the LUCT. Following this feasibility phase, an opportunity arose to apply the LUCT during a 'real time' vascular clinic, in order to evaluate template utility. A vascular surgeon, with a specific interest in the impact of CVLUs on QoL, requested that the template to be applied during a busy CVLU clinic. The LUCT simply provides a sequence of prompts to encourage the patient to disclose their concerns, this was agreed by the local Trust as a formal evaluation rather than further research that would require ethical approval.

Each patient attending the clinic undertook their usual consultation with the surgeon and TVN. This consultation had its' usual focus on the physical condition of the wound and the wound management strategy. During this initial contact, each patient had an approved physical wound assessment document completed. Nine patients attended the clinic for review and following their consultation, a further nurse, with the patients' permission, completed the LUCT. Findings from completion of the LUCT, when reported to the surgeon, resulted in a number of alterations to care for eight of the nine patients. On many occasions the changes made may appear minor, however, they were in response to patient disclosure and would have been significant for the patient:

- (i) Patient 1: disclosed dietary issues, compounded by a recent exacerbation of their CVLU and their ability to prepare their food. As a result, a re-referral to the patient's Diabetic Specialist was arranged.
- (ii) Patient 2: reported excessive pain, uncontrolled by their current analgesia regime. In response, a review of current medication led to the prescription of additional medication, Gabapentin, for neuropathic pain.
- (iii) Patient 3: reviewed following a partial foot amputation. The patient had been unable to shower over the last 6 weeks due to the dressing being in situ. A shower aid was prescribed.
- (iv) Patient 4: reported difficulties with wearing their shoes so a prescription was provided for Velcro boots as an interim measure, until the bulk of her dressing could be reduced.
- (v) Patient 5: reported feeling very low in mood, despite great family support. This had persisted for a number of weeks so a prescription for anti-depressants was issued and the patient referred back to her General Practitioner (GP) for further support.

(vi) Patient 6: disclosed that they were no longer managing alone at home with. A referral was made to Social Services for a review for further support from home care workers.

(vii) Patient 7: reflected on their inability to sleep, attributed to inactivity and pain during the night. Medication was reviewed, and advice given about timing.

(viii) Patient 8: disclosed they were no longer able to get upstairs to bed and had been sleeping in their chair in their lounge. The patient agreed to their bed being moved downstairs, as an interim measure, until more permanent arrangements could be put in place.

(ix) Patient 9: was very unwell, accompanied from a Nursing Home by her family. It was felt that in view of how sick she was it would be inappropriate for the LUCT to be completed.

Although findings from the phase 4 feasibility study demonstrated a small to medium effect on consultation satisfaction and QoL, the findings of this clinical evaluation are included here to demonstrate the impact that refocusing the consultation can have on patient care. Anecdotal feedback from the surgeon and TVN was that the LUCT was simple and fast to complete, providing opportunities and prompting for patients that effectively encouraged them to disclose issues that had previously been overlooked.

Discussion.

The findings in Part 1 of this series of two publications, clearly evidenced the devastating impact of CVLU for the patient, across physical, psychological and social functioning (Rich & McLachlan, 2003; Green et al, 2013 a & b; Franks et al, 2016). Observations of clinical consultations further demonstrated that, despite compromised QoL, 38% of patients did not disclose issues of concerns to their consulting nurse and, even when concerns were disclosed, on many occasions issues were not fully addressed (Green et al, 2018).

In response to the findings detailed in part 1, part 2 has presented the development of a consultation template, designed to focus the consultation on known QoL issues, using a consensus technique. A feasibility study of the utility of the new LUCT was undertaken, which demonstrated a small to medium effect on both satisfaction and QoL indicators. The phase 4 findings also corroborated phase 1 findings, demonstrating low baseline QoL scores for patient participants with CVLU in both their SF-12 [Physical Health score 34.65 (UK norm: 50.9) and Mental Health score 48.53 (UK norm: 52.1)] (Ware et al, 1996) and EQ-5D [0.57 (UK norm: 0.78 65-74 years)] (EuroQol, 1990) scores.

Application of the LUCT resulted in improving QoL and satisfaction scores; this was further strengthened by anecdotal feedback from staff following an application of the LUCT during a vascular clinic. This demonstrated that use of the LUCT may encourage deeper patient disclosure with a consulting HCP. Here, the completion of a standardised wound assessment and a routine consultation failed to reveal issues of importance to eight of nine patients, however use of the LUCT appeared to have provided patients with an opportunity to reveal more about issues that concerned them and, subsequently, led to a range of improvements in the care received.

Conclusion

As stated, measures to promote PCC within the consultation generally have one of two foci: changing practitioner behaviour (EPOC, 2008) or patient-mediated interventions (Irwin and Richards, 2006; Kinnersley et al, 2007). A review of standardised templates for the care of patients with CVLU reveal that they focus almost exclusively on the physical assessment of the patient and their wound, including the wound measurements, the detail of assessment and the characteristics of the wound (Wound, Ostomy & Continence Care Society, 2016). Such templates represent a medicalised approach to leg ulcer care and tend to direct the nurse away from holistic assessment of patient's needs; indeed, almost promoting a task focus (Beresford, 2010).

The LUCT was developed, based on study findings, to assist in the redressing of this balance; to enable the patient and the HCP to focus the consultation on issues and concerns that impact on the life of their patients - a PCC approach. The LUCT was designed in response to a lack of disclosure of QoL issues during CVLU patient consultations (Green et al, 2013b; Green et al, 2018), with the support of patient partners.

Some evidence of the impact of the LUCT on both the patients and HCPs has been demonstrated and reported here, however, this is an area where further research is required. Further developments of the LUCT will focus on developing an accessible version for patients to self-complete in advance of their nurse consultation and also the potential for the LUCT to provide a 'score', to inform clinicians of the impact of CVLU on a specific patient.

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